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PTO/SB/08A (10-96)

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Substitute for form 1449A/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

1

of

2

### Complete if Known

Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
Attorney Docket Number	00543-22

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	1	6,027,692		GALEN, et al.	01-22-2000	Entire Document
	2	5,997,476		BROWN	07-12-1999	Entire Document
	3	5,971,922		ARITA, et al.	10-26-1999	Entire Document
	4	5,822,935		HIRAI, et al.	03-16-1999	Entire Document
	5	5,251,126		KAHN, et al.	03-10-1993	Entire Document
	6	5,206,144		ZEUTHEN, et al.	04-27-1993	Entire Document
	7	6,081,786		BARRY, et al.	06-27-2000	Entire Document
	8	6,188,988		BARRY, et al.	02-13-2001	Entire Document
	9	5,431,793		WANG, et al.	07-11-1995	Entire Document
	10	5,453,379		YAMAZAKI, et al.	09-26-1995	Entire Document
	11	6,054,039		SHIEH	04-25-2000	Entire Document
	12	6,175,752		SAY, et al.	01-15-2001	Entire Document
	13	5,741,211		RENIRIE, et al.	04-21-1998	Entire Document
	14	5,108,564		SZUMINSKI, et al.	04-28-1992	Entire Document
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	18	4,731,726		ALLEN, III	03-15-1998	Entire Document
	19	6,272,480		TRESP, et al.	08-07-2001	Entire Document
	20	6,233,471		BERNER, et al.	05-15-2001	Entire Document

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			First Named Inventor	Boris P. Kovatchev, et al.	
			Group Art Unit	1652	
			Examiner Name	Unknown	
Sheet	2	of	2	Attorney Docket Number	00543-22

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	21	5,019,974		BECKER	05-28-1991	Entire Document
	22	5,840,020		HEINONEN et al.	11-24-1998	Entire Document
	23	5,748,851		IOKIBE et al.	05-05-1998	Entire Document
	24	5,989,409		KURNIK et al.	11-23-1999	Entire Document
	25	5,558,638		EVERS et al.	09-24-1996	Entire Document
	26	5,267,152		YANG, et al.	11-30-1993	Entire Document
	27	5,724,580		LEVIN, et al.	03-03-1998	Entire Document
	28	5,086,229		ROSENTHAL, et al.	02-04-1992	Entire Document
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	30	5,036,861		SEMBROWICH, et al.	08-06-1991	Entire Document
	31	5,076,273		SCHOENDORFER, et al.	12-31-1991	Entire Document
	32	5,140,985		SCHROEDER, et al.	08-25-1992	Entire Document
	33	5,279,543		GLIKFELD, et al.	01-19-1994	Entire Document
	34	5,822,715		WORTHINGTON, et al.	10-13-1998	Entire Document
	35	5,139,023		STANLEY, et al.	08-18-1992	Entire Document

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	36	EP	0834825		SALZSIEDER, et al.	04-08-1998	Entire Document	
	37	WO	0018289		CYGNUS, INC.	04-06-2000	Entire Document	
	38	WO	0019888		Reagents of Univ of CA	04-13-2000	Entire Document	
	39	WO	9929230		E.HELLER & CO.	06-17-1999	Entire Document	
	40	WO	0018293		Health Hero Network LLC	04-06-2000	Entire Document	
	41	WO	9600110		CYGNUS, Inc.	01-04-1996	Entire Document	
	42	DE	20305978 U 1		DITTLER, Jan	07-24-2003	Entire Document	
	43	GB	2159625 A		KREBS, Peter Eric	12-04-1985	Entire Document	

Examiner Signature	/Lori Clow/	Date Considered	02/15/2008
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Sheet 1 of 9

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Group Art Unit	1652
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## OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

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	A	COX, et al.: "Frequency of Severe Hypoglycemia in Insulin-Dependent Diabetes Mellitus Can be Predicted from Self-Monitoring Blood Glucose..." J of Clinical End. and Met., Vol. 79, No. 6, pp 1659-1662. (1994)	
	B	KOVATCHEV, et al.: "Assessment of Risk for Severe Hypoglycemia Among Adults with IDDM", Diabetes Care, Vol. 21, No. 11, November (1998)	
	C	KOVATCHEV, et al.: "Symmetrization of the Blood Glucose Measurement Scale and its Applications", Diabetes Care, Vol 20, No. 11, November (1997)	
	D	KOVATCHEV, et al.: "Risk Analysis of Blood Glucose Data: A Quantitative Approach to Optimizing the Control of Insulin Dependent Diabetes", J. of Theoretical Medicine, pp 1 - 10, January (2000)	
	E	<del>KOVATCHEV, et al.: "Episodes of Severe Hypoglycemia in IDDM are Preceded, and Followed, within 48 hours by Measurable Disturbances..."</del>	
	F	KOVATCHEV, et al.: "Assoc. of Self-Monitoring Blood Glucose Profiles with Glycosylated Hemoglobin in Patients...", Methods in Enzymology, Vol 321, pp 410-417, (2000)	
	G	LEHMANN, E.D., et al.: "Computer assisted diabetes care: a 6-year retrospective", Computer Methods and Programs in Biomedicine, 50, 209-230 (1996)	
	H	DEUTSCH, T., et al.: "Time series analysis and control of blood glucose levels in diabetic patients", Computer Methods and Programs in Biomedicine, 41, 167-182 (1994)	
	I	LEHMANN, E.D., et al.: "AIDA: an interactive diabetes advisor", Computer Methods and Programs in Biomedicine, 41, 183-203, (1994)	
	J	LEHMANN, E.D., et al.: "Retrospective validation of physiological model of glucose-insulin interaction in type 1 diabetes mellitus", Med. Eng. Phys., Vol. 16, 193-202, May (1994)	
	K	LEHMANN, E.D., et al.: "Extended Conference Report: Computers in Diabetes '96", Med. Inform, Vol. 22, No. 1, 105-118, (1997)	

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Sheet 2 of 9

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First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	L	LEHMANN, E.D., et al.: "Application of computers in diabetes care -- a review. I. Computers for data collection and interpretation", Vol. 20, No. 4, 281-302, (1995)	
	M	DEUTSCH, T. et al.: "UTOPIA: a consultation system for visit-by-visit diabetes management", Med Inform, Vol. 21, No. 4, 345-358 (1996)	
	N	LEHMANN, E.D., et al.: "Compartmental models for glycaemic prediction and decision-support in clinical diabetes care: promise and reality" Computer Methods and Programs in Biomedicine, Vol. 56, 193-204, (1998)	
	O	LEHMANN, E.D., et al.: "A physiological model of glucose--insulin interaction in type 1 diabetes mellitus", J. of Biomedical Engineering Vol. 14, No. 3, 235-242 (1992)	
	P	TRAJANOSKI, ZLATKO, et al.: "Simulation studies on neural predictive control of glucose using the subcutaneous route", Comp Methods and Programs in Biomed., Vol. 56, Iss 2, 133-139, May (1998)	
	Q	TRAJANOSKI, ZLATKO, et al.: "Fuzzy filter for state estimation of a glucoregulatory system", Comp. Methods and Programs in Biomedicine, Vol. 50, 265-273, (1996)	
	R	TRAJANOSKI, ZLATKO, et al.: "Regularization networks for Glucose System Identification", Institute of Biomedical Engineering, 1083- , 0-7803-2050-6/94 ABSTRACT ONLY	
	S	REGITTNIG, W. et al.: "Glucose-mediated glucose disappearance during the intravenous...", 18th Annual International Conference of the IEEE Eng. in Medicine and Biology Society, Amsterdam, 0-7803-3811-1/97 1996 (annotated by examiner LAC)	
	T	FISCHER, UWE, et al.: "Experimental validation of a glucose- insulin control model to simulate patterns in glucose turnover", Comp. Methods and Programs in Biomedicine, Vol. 32, 249-258 (1990)	
	U	SALZSIEDER, E., et al.: "A Model-based System for the Individual Prediction of Metabolic Responses to Improve Therapy in Type 1 Diabetes", Central Inst. of Diabetes, Horm. Metab. Res, 24 (Suppl) 10-19 (1990)	
	V	SALZSIEDER, ECKHARD, et al.: "Computer-aided systems in the management of type I diabetes: the application of a model-based strategy", Computer Methods and Programs in Biomedicine, Vol. 32, 215-224, (1990)	

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	W	<del>SALZSIEDER, ECKHARD, et al.: "Model-Based Prevention in IDDM of Exercise-Induced Hypoglycemia". ABSTRACT ONLY</del>	
	X	BLECKERT, GABRIELE, et al.: "Mixed graphical models for simultaneous model identification and control applied to the glucose-insulin metabolism", Computer Method and Programs in Biomed Vol. 56, 141-155 (1998)	
	Y	MARTIN, IVA K, et al.: "Application of the SAAM modeling program to minimal model analysis of intravenous glucose tolerance test data", Computer Methods and Programs in Biomedicine, Vol. 33 193-203(1990)	
	Z	WARD, G. M., et al.: "Physiologic Modeling of the Intravenous Glucose Tolerance Test in Type 2 Diabetes: A new Approach to the Insulin Compartment", Metabolism, Vol 50, No. 5, 512-519, May (2001)	
	AA	WARD, G. M., et al.: "A Modified Minimal Model Analysis of Insulin Sensitivity and Glucose-Mediated Glucose Disposal in Insulin-Dependent Diabetes", Metabolism, Vol. 40, No. 1, 4-9, January (1991)	
	BB	THOMASETH, KARL, et al.: "Parameter Information Content During Model Identification Experiments", 3rd IFAC Symposium on Modelling and Control in Biomedical Systems, Warwick UK, 107-112 (1997)	
	CC	PACINI, GIOVANNI, et al.: "Estimation of B-cell Secretion and insulin hepatic extraction by the minimal modelling technique", Computer Methods and Programs in Biomedicine, Vol. 32, 241-248 (1990)	
	DD	BELLAZZI, R., et al.: "Bayesian Analysis of Blood Glucose Time Series from Diabetes Home Monitoring", IEEE Transactions on Biomedical Engineering, Vol. 47, No. 7, 971-, July (2000)	
	EE	BELLAZZI, R, et al.: "The Subcutaneous Route to Insulin-Dependent Diabetes Therapy", IEEE Engineering in Med. and Bio., Vol. 20, No. 1, 54-64, Jan (2001)	
	FF	RIVA, A., et al.: "High Level Control Strategies for Diabetes Therapy", Proceedings of the Fifth Conference on Artificial Intelligence in Medicine Europe, No. 934 in Lecture Notes in Artificial Intelligence, p 185-196, (1995)	
	GG	ARLETH, T. et al.: "A model of the edogenous glucose balance incorporating the characteristics of glucose transporters", Computer Methods and Programs in Biomedicine, Vol. 62, 219-234, (2000)	

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	HH	STURIS, JEPPE, et al.: "Computer model for mechanisms underlying ultradian oscillations of insulin and glucose", Am. J. of Physiol., Modeling Methodology Forum, E801-E809, (1991)	
	II	QUON, MICHAEL, et al.: "Non-Insulin-Mediated Glucose Disappearance in Subjects with IDDM Discordance Between...", Diabetes, Vol. 43, 890-, July (1994)	
	JJ	MUZIC, R. et al.: "COMKAT: Compartment Model Kinetic Analysis Tool", The Journal of Nuclear Medicine, Vol. 42, No. 4, April (2001)	
	KK	FREELAND, ANGELA, et al.: "Inference of Blood Glucose Concentrations from Subcutaneous Glucose...", Annals of Biomedical Engineering, Vol. 27, 525-537, (1999)	
	LL	BERGER, MARCUS, et al.: "Computer Simulation of Plasma Insulin and Glucose Dynamics After Subcutaneous Insulin Injection", Diabetes Care, Vol. 12, No. 10, November (1989)	
	MM	FINEGOOD, D., et al.: "Reduced glucose effectiveness associated with reduced insulin release: an artifact of the minimal-model method", Am. J. of Physiol. Endocrin. Metab. 271, E485-E495, (1996)	
	NN	NAYLOR, J. S., et al.: "Comparison of parametrized models for computer-based estimation of diabetic patient glucose response", Med. Inform., Vol. 22, No. 1, 21-34, (1997)	
	OO	ANDREASSEN, S.: "Model-Based Biosignal Interpretation", Meth Inform Med, Vol. 33, 103-110, (1994)	
	PP	WORTHINGTON, D.: "The use of models in the self-management of insulin-dependent diabetes mellitus", Computer Methods and Programs in Biomedicine, Vol. 32, 233-239, (1990)	
	QQ	CARSON, E.R.: "Information technology and computer-based decision support in diabetic management", Computer Methods and Programs in Biomedicine, Vol. 32, 179-188, (1990)	
	RR	GOMEZ, E.J, et al.: "Telemedicine for diabetes care: the DIABTel approach towards diabetes telecare", Med. Inform., Vol. 21, No. 4, 283-295, (1996)	

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	SS	TRAJANOSKI, ZLATKO, et al.: "Neural Predictive Controller for Insulin Delivery Using the Subcutaneous Route", IEEE Transactions on Biomedical Engineering, Vol. 45, No. 9, September (1998)	
	TT	BERGER, M.P.: "Combining Statistical, Rule-Based, and Physiologic Model-Based Methods to Assist in the Management...", Computer and Biomedical Research, Vol. 23, 346-357, (1990)	
	UU	FISHER, MICHAEL: "A Semiclosed-Loop Algorithm for the Control of Blood Glucose Levels in Diabetics", IEEE Transactions on Biomedical Engineering, Vol. 38, No. 1, January 1991	
	VV	HERNANDO, M.E. et al.: "DIABNET, a qualitative model-based advisory system for therapy planning in gestational diabetes", Med. Inform. Vol. 21, No. 4, 359-374, (1996)	
	WW	KIENITZ, Karl H., et al.: "A Robust Controller for Insulin Pumps Based on H-Infinity Theory", IEEE Transactions on Biomedical Engineering, Vol. 40, No. 11, November (1993)	
	XX	PARKER, ROBERT, et al.: "Control-relevant modeling in drug delivery", Advanced Drug Delivery Reviews, Vol. 48, 211-228, (2001)	
	YY	CARSON, E.R., et al.: "Computers in Diabetes - an Introduction", Computer Meth Prg. Biomed., Vol. 62, 153-155, (2000)	
	ZZ	HAUSER, THOMAS, et al.: "Assessment of Experts' Approach to Insulin Therapy...", Diabetes Care, Vol. 15, No. 2, pp 221-, February (1992)	
	aaa	GARCIA, ALEJANDRO: "The Bergman's Insulin-Glucose Regulation Model: DNN-state Observer", Proceedings of the 22nd Annual EMBS International Conf., July 23-28, Chicago, IL. (2000)	
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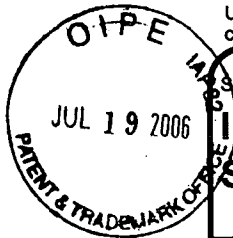
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Sheet 6 of 9

**Complete if Known**

Application Number	10/524,094
Filing Date	2/9/2005
First Named Inventor	Boris P. Kovatchev, et al.
Group Art Unit	1652
Examiner Name	Unknown
Attorney Docket Number	00543-22

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	ddd	PARKER, ROBERT S., et al.: "The Intravenous Route to Blood Glucose Control", IEEE Engineering in Medicine and Biology, pp 65-, January (2001)	
	eee	PARKER, ROBERT S., et al.: "A Model-Based Algorithm for Blood Glucose Control in Type 1 Diabetic Patients", IEEE Transactions on Biomedical Engineering, Vol. 46, No. 2, pp 148-, February (1998)	
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	iii	ROBINSON, DAVID, et al.: "Knowledge of Diabetes mellitus and glycaemic control", Med. Principles Pract. Vol. 6, 186-197 (1997)	
	jjj	TOTH, MICHAEL, et al.: "Determinants of insulin-stimulated glucose disposal in middle-aged, premenopausal women", Am J Physiol Endocrinol Metab., Vol. 281, E113-E121, (2001)	
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	uuu	DASU, TK., "Computer Simulation of Blood Glucose Level in Stress Conditions", pp 491 ABSTRACT ONLY	
	ppp	TRESP, Volker, et al.: "Neural-Network Models for the Blood Glucose Metabolism of a Diabetic", IEEE Transactions on Neural Networks, Vol. 10, No. 5, pp 1204-1213, September (1999)	
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	ttt	HEJLESEN, Ole, et al.: "Analysing the hypoglycaemic counter-regulation: a clinically relevant phenomenon?", Computer Methods and Programs in Biomedicine, Vol. 50, 231-240, (1996)	
	uuu	HEJLESEN, Ole, et al.: "Dynamic Propagation in Causal Problistic networks with Instantiated Variable", Artificial Intelligence in Medicine: Proceedings of the 5th Conference on Artificial Intelligence in Medicine, 151-162, (1995)	
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	w3	ANDREASSEN, STEEN, et al.: "A probabilistic approach to glucose prediction and insulin dose adjustment; description of metabolic model and pilot evaluation study", Computer Methods and Programs in Biomedicine, Vol. 41, 153-165, (1994)	
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	yyy	GOLD, A.E., et al.: "A Structural Equation Model for Predictors of Severe Hypoglycaemia in Patients with Insulin-dependent Diabetes Mellitus", Diabetic medicine, Vol. 14, 309-315, (1997)	

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	zzz	BREMER, TROY, et al.: "Is Blood Glucose Predictable from Previous Values? A solicitation for data", Diabetes, Vol. 48, pp 445-451, March (1999)	
	I	BOYLE, PATRICK, et al.: "Plasma Glucose Concentrations at the onset of Hypoglycemic symptoms in Patients with Poorly Controlled Diabetes and in Nondiabetics", Plasma Glucose Concentrations and Hypoglycemia, Vol. 318, No. 33, 1487-1492, (1988)	
	II	CARSON, EWART: "A systems model of Blood Glucose control", Int. J. Bio-Medical computing, Vol. 7, pp 21-34, (1976)	
	III	WORTHINGTON, D.R.L.: "Minimal Model of Food Absorption in the gut", Med. Inform., Vol. 22, No. 1, 35-45 (1997)	
	IV	WORTHINGTON, D.R.L.: "Controlling blood Glucose: insights from an engineering control systems perspective", Med. Inform. Vol. 22, No. 1, 5-19 (1997)	
	V	DCCT RESEARCH GROUP: "The effect of intensive treatment of diabetes on the development and progression of Long-term complications of insulin-dependent diabetes Mellitus", New England Journal of Medicine, Vol. 329, 977-986 (1993)	
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	X	CRYER, PE: "Hypoglycemia is the limiting factor in the management of Diabetes", Diabetes Metab Res Rev, Vol. 15, 42-46, (1999)	

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	XI	SVENDSON, AABY, et al.: "Glycosylated Hemoglobin and Steady-State Mean Blood Glucose Concentration in Type 1 (Insulin-Dependent) Diabetes", Diabetologia, Vol. 23, 403-405, (1982)	
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	XIV	BREMER, T, et al.: "Is blood glucose predictable from previous values? A solicitation for data", Diabetes, Vol. 48, 445-451, (1999)	
	XV	KOVATCHEV, B.P., et al.: "Estimating the speed of Blood Glucose Transitions and its relationship with Severe Hypoglycemia", Diabetes, 48: Supplement 1, A363, (1999)	

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